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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* NO. 10 TO EXCLUDE EVIDENCE THAT DEFENDANTS NEEDED FDA CONSENT BEFORE ADDING A WARNING TO ITS LABELING OR ISSUE A RECALL

(Assigned to the Honorable David G. Campbell)

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Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") submit this response in opposition to Plaintiff's Motion *in Limine* No. 10 and respectfully show the Court as follows:

ARGUMENT AND CITATION OF AUTHORITY

First, regarding labeling changes, the Plaintiff's Motion ignores 21 C.F.R. § 807.81(a)(3), which requires manufacturers to give "premarket notification" to FDA prior to any "significant[]" change or modification to the "design, components, method of manufacture, or intended use" of the device. *See* 21 C.F.R. §807.81(a)(3). This includes a labeling change "meant to significantly improve clinical outcomes, to mitigate a known risk, or in response to adverse events," which change "likely requires submission of a new 510(k)." *See* FDA's Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device," at p. 19 (Oct. 25, 2017), attached hereto as Exhibit A.

Plaintiff's Motion argues that Bard could have added warnings regarding "the increased risks" of complications "associated with its products." (Pl's. Mot. at 2.) The Plaintiff's concept of "increased risks" necessarily requires a comparison, such as a comparison between Bard's G2® Filter and competitive devices based on MDR or MAUDE data. But, FDA regulations govern what content may be used in IFUs, and the Plaintiff's proposed warning changes run afoul of these regulations. For example, 21 C.F.R. § 201.57(c)(7) (2011) states that "any claim ***comparing*** the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies defined in § 314.126(b)." (emphasis added). 21 C.F.R. § 314.126(b) lists numerous study control requirements that must be met and that are not acquired via MAUDE data. FDA also recognizes that the MAUDE database cannot be used to compare incidence rates, stating that "MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of

problems associated with devices."[1] Finally, when Dr. Suzanne Parisian – the Plaintiff's own regulatory expert – was asked "you would not put the comparison based only on the MAUDE database into your labeling, would you?" she responded, "No. You could use medical literature . . . But the MAUDE database, it can be used for certain things, but it's not -- you wouldn't use it across industry to come up with the incidence rate." September 25, 2014 Dep. Tr. Dr. Suzanne Parisian, at 71:5-18, attached hereto as Exhibit B.

Bard acknowledges that, in the summary judgment context, this Court found Bard could not "overcome the presumption against preemption" and meet the "demanding defense" of impossibility preemption by demonstrating that "any labeling changes" required by state law are impossible to execute without FDA concurrence. (Doc. 8872 at 24-25). But whether "any labeling changes" could be made without FDA concurrence, or whether a labeling change to include comparative rate information—which Plaintiff is advocating here—requires FDA clearance are very distinct concepts. The latter would require FDA clearance, if the FDA would allow it at all, and the jury should be given this highly probative information to determine whether Bard should have, ***or even could have***, revised its warnings as the Plaintiff advocates.[2]

Second, regarding evidence or testimony concerning product recalls, Bard does not dispute that a manufacturer may voluntarily initiate a recall pursuant to 21 C.F.R. § 7.46. But the fact that a manufacturer may voluntarily initiate a recall is only part of the picture. The regulation cited by the Plaintiff, 21 C.F.R. § 7.46, makes several clear statements regarding FDA's role in voluntary recalls, noting several agency actions that never happened with Bard's G2® Filter. 21 C.F.R. § 7.46(a) states that "[s]uch removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action." Further, 21 C.F.R. §

[1] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last accessed Feb. 5, 2018).

[2] FDA's own actions with Bard demonstrates that it expects manufacturers to collaborate with the agency in drafting and revising its IFU and Dear Doctor Letters before instituting any changes to the labeling of IVC filters. *See, e.g.*, Bard's Separate Statement of Facts in Support of Preemption Motion (Doc. 5398), at ¶¶ 103-104, 111-117, 119-129, 133-139, 190-191, 196-201, 230-231, and 240-242.

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7.46(c) states that "[a] firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law." And in situations where 21 C.F.R. § 7.46(d) applies, "the Food and Drug Administration will assist the firm in determining the exact nature of the problem." *Id.*

The fact that FDA requires that manufacturers work with the agency when implementing voluntary recalls is critical to put into context the Plaintiff's claim that Bard independently should have voluntarily recalled any of its filters.[3] This evidence is further critical to explain to the jury FDA's involvement in a medical device's marketing, including whether that device is recalled from the market. Thus, Bard should be permitted to offer evidence of why Bard's IVC filters were not recalled, including the fact that (a) FDA never suggested Bard should voluntarily recall its IVC filters due to complications such as migration, fracture, tilt, or perforation; (b) FDA never mandated a recall;[4] and (c) Bard could not have effectuated a recall without FDA involvement. This evidence is relevant for the jury to consider whether Bard's decision and actions to keep its G2® Filter on the market (i.e., to not recall it) were reasonable, as well as to the issue of punitive damages. *Cf. O'Neill v. Novartis Consumer Health, Inc.*, 147 Cal. App. 4th 1388, 1393 (2007) ("FDA action or inaction, though not dispositive, may be considered to show whether a product is safe or not safe.").

CONCLUSION

For these reasons, Bard respectfully requests that this Court deny Plaintiff's Motion *in Limine* No. 10.

[3] Of note, Plaintiff misconstrues Ms. Hudnall's testimony regarding the transition from the Recovery® Filter to the G2® Filter. The Recovery® Filter was not voluntarily recalled as Plaintiff implies, and Ms. Hudnall's preceding testimony which Plaintiff omits clarifies that the Recovery Filter was not taken off the market because of complication rates, but that "[t]he G2 filter was the next generation of the Recovery filter. So [Bard] didn't keep previous generation and new generation at the same time." Deposition of Janet Hudnall, attached hereto as Exhibit C, at 135:5-14.

[4] FDA has the power to mandate a medical device recall pursuant to 21 C.F.R. § 810.10, which provides that FDA may "issue a cease distribution and notification order" to a manufacturer. *See also* FDA's Regulatory Procedures Manual at Section 7-5-3 (entitled "FDA Mandated Recalls"), available at https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ (last accessed Feb. 5, 2018).

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RESPECTFULLY SUBMITTED this 9th day of February, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of February, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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